DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 22, 2015

Deltex Medical Limited
% Neil Armstrong
RA Advisor To Deltex Medical
Meddiquest Limited
Quest Science, Orton Malborne
Peterborough, PE2 5XS GB

Re: K142932
Trade/Device Name: Deltex Medical KDP72 Doppler Probe
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular Blood Flow Probe
Regulatory Class: Class II
Product Code: DPT
Dated: October 10, 2014
Received: October 14, 2014

Dear Neil Armstrong,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Unknown - not yet assigned by FDA

Device Name
KDP72, 72 Hour Doppler Probe

Indications for Use *(Describe)*
The probe is for use with the Deltex Medical CardioQ-EDM and CardioQ-EDM+ for Monitoring of cardiac output and fluid status. The probe is only approved for oral placement into the esophagus of a single anesthetized patient 15 years of age or younger, 50cm (20") to 170cm (67") in height.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Contains Nonbinding Recommendations
Appendix G

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: CardioQ-EDM and CardioQ-EDM+ cardiac output and fluid status monitor
Transducer: KDP72 , 72 Hour Doppler Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)				N			
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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510(k) Summary
as required by 21 CFR 807.92(c)

Submitter and Owner:
This Premarket Notification, 510(k), is submitted by:

Graham Lowe
Marketing and Operations Director

For and on behalf of the Owner:

Deltex Medical Ltd
Terminus Road
Chichester
West Sussex PO19 8TX
United Kingdom
Tel: 011 44 1243 523174
Fax: 011 44 1243 532534

Date

This Summary was prepared on September 22, 2014

Classification name:

Extravascular blood flow probe

The FDA has classified: “Extravascular blood flow probe” in 21 CFR 870.2120 as a Class II medical device with Product Code DPT

Common/Usual Name:

probe, blood-flow, extravascular

Proprietary Name:

Deltex Medical Ltd KDP72 Doppler Probe

Establishment Registration Number:

The device will be manufactured by:

Deltex Medical Ltd
Terminus Road
Chichester
West Sussex
PO19 8TX
United Kingdom
Establishment Registration Number 9680933

and sterilized by:

Sterigenics UK, Ltd
Cotes Park Estate
Somercotes
Derbyshire DE55 4NJ
United Kingdom
Establishment Registration Number 3002807091

Substantial Equivalence:

The Deltex Medical Ltd KDP72 Doppler Probe is substantially equivalent in design, use and materials to the:

Deltex Medical Ltd I_2n Series Doppler Probe – K073593
Deltex Medical Ltd DP240 Doppler Probe – K052989 and the
Sometic Dynemo 3000 - K972798, now Arrow Hemosonic probe

Like the I_2n Series Probe is for use with the Deltex Medical CardioQ-EDM and CardioQ-EDM+ systems, K111542 and K132139 respectively.

The Deltex Medical Ltd KDP72 Pediatric Doppler Probe is designed to be a shorter version of the current legally marketed Dp240 product with more depth markings. It has an open-coil spring, as used on the I2 series products instead of the closed coil used on the Dp240, to increase flexibility.

The Sometic Dynemo 3000 K972798 has been superseded by the Arrow Hemosonic probe (still K972798) which is indicated for pediatric use for patients above 15kg. The Deltex Medical Ltd KDP72 will be shorter and more flexible enabling it to be indicated for patients above 3kg.

Description:

The Deltex Medical Ltd KDP72 Pediatric Doppler Probe is an oral extravascular blood flow probe designed to work with the CardioQ-EDM and CardioQ-EDM+ Systems (K111542 and K132139 respectively). It consists of a shaft, which is a spring reinforced silicone tube, with an electrical connector on the machine end and an ultrasonic transmitting and receiving tip on the patient end. The tip is fully covered and sealed to the shaft with a silicone rubber boot and by wires running through the shaft to the connector. Visual product identification is provided at the machine end and the device is provided single packed sterile for single patient use.

Standard ultrasonic diagnostic extravascular blood flow probes have been successfully used with pediatric patients; however the KDP72 has been specially designed for pediatric patients with a shorter length, more depth markings and an open coil spring to increase the flexibility.

Intended Use:

The probe is for use with Deltex Medical CardioQ-EDM and CardioQ-EDM+ for monitoring of cardiac output and fluid status. The probe is only approved for oral placement into the esophagus of a single anesthetized patient 15 years of age or younger.

Performance Data

The performance data recommended in “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers”, issued on September 9, 2008, has been included.

Additionally a flexibility test has been conducted on the subject and predicate devices which demonstrates the comparative flexibility.

Conclusion

Based on the information above, Deltex Medical Ltd concludes that the Deltex Medical Ltd KDP72 Doppler Probe in substantially equivalent to:

- the Deltex Medical Ltd I2 Series and Dp240 Doppler Probes (K073593 and K052989), and
- the Arrow International, Inc, Hemosonic 100 Esophageal Probe (K972798 Sometic Dynemo 3000).

Feature	Deltex Medical 'KDP72' Subject Device	Deltex Medical 'I$_2$n-series' Predicate Device #1	Deltex Medical 'DP240' Predicate Device #2	Arrow 'Hemosonic 100 Esophageal Probe' Predicate Device #3
FDA 510k number	This Submission	K073593	K052989	K972798
product name	KDP72	I$_2$n-series	DP240 Probe	Transesophageal Probe
common name	72 Hour Pediatric Doppler probe	I$_2$n-series Doppler probe	240 Hour Doppler Probe	Trans-esophageal Probe & Sterile Jacket
product number	9081-7002	9090 – 7015 9090 – 7016 9090 - 7017	9070- 7006	HSP – 02150 & HSS-02150
Device Description				
Sterilization	Sterilized in accordance with ISO11135-1 (version of standard current at time of submission)	Sterilized in accordance with ISO11135-1 (version of standard current at time of submission)	Sterilized in accordance with ISO11135-1 (version of standard current at time of submission)	Unknown
Shelf Life	ISO11607-1 (version of standard current at time of submission)	ISO11607-1 (version of standard current at time of submission)	ISO11607-1 (version of standard current at time of submission)	Unknown
Biocompatibility	Tested in accordance with ISO 10993-5, ISO 10993-10, ISO 10993-7 (version of standard current at time of submission)	Tested in accordance with ISO 10993-5, ISO 10993-10, ISO 10993-7 (version of standard current at time of submission)	Tested in accordance with ISO 10993-5, ISO 10993-10, ISO 10993-7 (version of standard current at time of submission)	Unknown
EMC and Electrical Safety	IEC60601-1, IEC60601-1-2, IEC606001-2-37 (version of standard current at time of submission)	IEC60601-1, IEC60601-1-2, IEC606001-2-37 (version of standard current at time of submission)	IEC60601-1, IEC60601-1-2, IEC606001-2-37 (version of standard current at time of submission)	Unknown
Packaging	ISO 11607-1, ISO 11607-2 (version of standard current at time of submission)	ISO 11607-1, ISO 11607-2 (version of standard current at time of submission)	ISO 11607-1, ISO 11607-2 (version of standard current at time of submission)	Unknown